



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-1896]

Quality Metrics Site Visit Program for Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research Staff; Information Available to Industry

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) in the Food and Drug Administration (FDA or Agency) are announcing a 2018 CDER and CBER staff experiential learning site visit program specific to FDA's Quality Metrics Program. FDA is proposing this program, in part, in response to input from a variety of stakeholders over the past couple of years. The purpose of this 2018 Quality Metrics Site Visit Program is to provide experiential and firsthand learning opportunities to FDA staff involved in the development of the FDA Quality Metrics Program and to provide stakeholders with an opportunity to explain the advantages and challenges associated with implementing and managing a robust Quality Metrics Program. This notice invites pharmaceutical companies interested in participating in this program to submit a Quality Metrics Site Visit proposal.

DATES: Submit either an electronic or written proposal to participate in this program by

[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL*

REGISTER]. See section IV of this notice for information on what to include in such proposals.

FOR FURTHER INFORMATION CONTACT: Tara Gooen Bizjak, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2109, Silver Spring, MD 20993-0002, 301-796-3257, email: Tara.Gooen@fda.hhs.gov or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7268, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

More than a decade ago, FDA launched an initiative to encourage the implementation of a modern, risk-based pharmaceutical quality assessment system. As part of this initiative, and in recognition of the increasing complexity of pharmaceutical manufacturing, FDA developed a 21st century vision for manufacturing and quality with input from academia and industry. The desired state was described as follows: “A maximally efficient, agile, flexible pharmaceutical manufacturing sector that reliably produces high-quality drug products without extensive regulatory oversight.”¹

There has been significant progress toward this vision in the intervening years as evidenced by programs and guidances from FDA around major initiatives such as pharmaceutical development and quality by design, quality risk management and pharmaceutical quality systems, process validation, and emerging technology, among others. These programs and guidances are intended to promote effective use of the modern pharmaceutical science and engineering principles and knowledge throughout the life cycle of a product.

¹ See “FDA Pharmaceutical Quality Oversight: One Quality Voice” at <https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/UCM442666.pdf>.

FDA sought input from industry on the establishment of an FDA Quality Metrics Program as another mechanism to promote continual improvement in manufacturing quality. FDA has also consulted with other stakeholders to identify mutually useful and objective quality metrics. The Agency heard that it should perform further studies of existing quality metrics programs and conduct additional discussions with stakeholders. Based on this input, CDER and CBER are initiating this 2018 Quality Metrics Site Visit Program to assist the Agency in understanding existing programs. This voluntary site visit program is designed to offer experiential and firsthand learning opportunities to CDER and CBER staff involved in the development of FDA's Quality Metrics Program and to provide stakeholders with an opportunity to explain the advantages and challenges associated with implementing and managing a robust quality metrics program. One goal of these visits is to provide CDER and CBER staff exposure to existing quality metrics programs through onsite visits, tour of operations, and discussions with establishments to assist staff in further developing FDA's Quality Metrics Program. Another goal is to provide a forum for industry to engage in the process and provide additional feedback into improving the FDA Quality Metrics Program.

II. The Site Visit Program

During a quality metrics site visit, CDER and CBER staff will observe how quality metrics data are gathered, collected, and reported to management. We anticipate 5 to 10 FDA representatives (involved in the development of FDA's Quality Metrics Program) would participate in a site visit taking place over a 1-to 2-day period. To facilitate the learning process, the host establishment may present overviews of the development and management of their quality metrics program. The presentation(s) will allow the participating establishments an opportunity to showcase technologies that support their program.

CDER and CBER encourage covered establishments, including establishments that do not perform physical manipulation of drugs, engaging in the development and manufacturing of both active pharmaceutical ingredients (small and large molecules) and drug products to submit quality metrics site visit proposals. A covered establishment is an owner or operator of an establishment that is engaged in the manufacture, preparation, propagation, compounding, or processing of a covered drug product, or an active pharmaceutical ingredient (API) used in the manufacture of a covered drug product. CDER and CBER staff participating in this program will benefit by gaining a better understanding of current industry practices, processes, and procedures for quality metrics programs.

CDER and CBER identified a number of establishment types that are of particular interest to their staff. The following list identifies some examples of these establishments but is not intended to be exhaustive, mutually exclusive, or to limit industry response to the notice:

- Manufacturer of brand, generic, biotechnology, APIs, and non-application product(s) marketed under the over-the-counter (OTC) monograph system, and any combination of these products;
- contract development and manufacturing organizations;
- establishments with small and large portfolios; and
- establishments with past or current product availability issues (e.g., history of a drug supply issue, recall).

The Quality Metrics Site Visit Program does not supplement or replace a regulatory inspection (e.g., a preapproval inspection, pre-license inspection, or a surveillance inspection).

III. Site Selection

Selection of potential facilities will be based on the priorities developed for CDER and CBER staff training, the facility's current compliance status with FDA, and in consultation with the appropriate FDA district office. All travel expenses associated with this program will be the responsibility of FDA; therefore, selection will be based on the availability of funds and resources for the fiscal year. FDA will not provide financial compensation to the pharmaceutical site as part of this program.

IV. Proposals for Participation

Companies interested in offering a site visit or learning more about this site visit program should respond by submitting a proposal directly to Tara Gooen Bizjak or Stephen Ripley (see FOR FURTHER INFORMATION CONTACT). To aid in FDA's site selection and planning, your proposal should include the following information:

- A contact person;
- site visit location(s);
- Facility Establishment Identifier and Data Universal Numbering System numbers, as applicable;
- maximum number of FDA staff that can be accommodated during a site visit (maximum of 10),
- a description of the development, history, and ongoing management of the quality metrics program;
- a sample agenda outlining the proposed learning objectives and associated activities for the site visit; and
- preferred dates for a quality metrics site visit.

Proposals submitted without this minimum information will not be considered.

Dated: June 25, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-14006 Filed: 6/28/2018 8:45 am; Publication Date: 6/29/2018]